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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98 N-0336]

Agency Information Collection Activities; Announcement of OMB Approval; Premarket Notification Submission 510(k), Subpart E

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled 'Premarket Notification Submission 510(k), Subpart E" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 30-827-1223.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 1, 1998 (63 FR 46462), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

OMB has now approved the information collection and has assigned OMB control number 0910 0120. The approval expires on October 31, 2001.

Dated: 12-43-41/1918

November 11, 1998

William K. Hubbard

Associate Commissioner for Policy Coordination

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